FINAL PROGRESS REPORT

Exploratory and Developmental Grant to Improve Health Care Quality through Health Information Technology: Surgical Risk Preoperative Assessment System (SURPAS)

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STRUCTURED ABSTRACT (word count 198)

Purpose:

This project focuses on the development, initial testing, dissemination, implementation, and evaluation of an information technology-based, patient-centric, preoperative, surgical risk assessment and decision support tool, the "**SU**rgical **R**isk **P**reoperative **A**ssessment **S**ystem" (SURPAS).

Scope:

This was performed in an academic hospital's surgical department.

Methods:

We engaged stakeholders (hospital administrative leadership, surgical providers, patients) through focus groups and interviews to identify facilitators and barriers to SURPAS implementation, and optimized the design of SURPAS in the local electronic health record (EHR). We implemented SURPAS on a limited basis, subsequently refining it. We used this experience to develop a dissemination and implementation proposal for scaling-up of SURPAS for use at our multi-hospital health system.

Results:

We successfully developed a user-friendly SURPAS interface in the local EHR. Information from stakeholders optimized the functionality of SURPAS for providers and patients. Patients and providers found SURPAS to be useful for preoperative risk assessment. SURPAS improved patients' understanding and comfort with planned operations and the shared-decision making process in the preoperative care environment. The findings from the limited implementation of SURPAS are guiding our scaling-up of SURPAS for dissemination and implementation in our broader health system.

Key Words: Surgical Risk Preoperative Assessment; Qualitative Methods; Preoperative risk prediction; unplanned readmission; postoperative mortality and morbidity

PURPOSE

Long-term Objectives: This project is the first in a series for the design, development, initial testing, dissemination and implementation, and evaluation (employing a large-scale pragmatic trial) of an information technology-based, patient-centric, preoperative, surgical risk assessment and decision support tool. We termed this patient-centric tool, the "SUrgical Risk Preoperative Assessment System" (SURPAS). Our long-term goal is to demonstrate that the preoperative provision of quantitative estimates of the risk of adverse operative outcomes to the surgical team, patient, and relevant hospital personnel leads to improved operative outcomes and reduces cost. If successful this approach will represent a paradigm shift in the way surgical risk is determined and shared with patients and providers preoperatively. Specific Aim 1: Apply an existing theoretical model of health information technology usage behavior to engage stakeholders, who include representatives of: a) Department of Surgery and University of Colorado Hospital (UCH) administrative leadership; b) Surgical teams composed of physicians, nurses, physician assistants, etc.; and c) Surgical patients. A combination of group meetings, structured interviews and focus groups were be conducted to: a) Identify facilitators and barriers to SURPAS implementation; b) Design and implement SURPAS to support existing care and quality improvement programs; c) Be able to communicate effectively SURPAS goals and design to hospital leadership and

staff; and d) Effectively communicate risk of proposed surgery to patients.

Specific Aim 2: Develop, implement on a limited basis, and refine SURPAS at UCH. Tasks included: a) Develop risk models to predict outcomes, which are parsimonious in their data requirements (completed with internal funding); b) Identify, map and validate the predictive variables available in the UCH Epic electronic health record (EHR); c) Develop software tools for real-time extraction of these data, facilitate entry by the surgical team of a limited set of key predictive variables not available in the EHR, and package these data as a statement of operative risk for inclusion in the preoperative note; d) Employ the AHRQ-supported Patient Education Materials Assessment Tool to maximize patient understandability and actionability of the CDS in SURPAS; e) Implement initial delivery methods to providers and patients at the point-of-care; and f) Monitor SURPAS CDS application, data integrity, performance and efficacy. Specific Aim 3: Towards our long-term goal stated above, we are using information generated by this study to develop a dissemination and implementation (D&I) proposal. This will be conducted within the University of Colorado Health System (UCHealth), a partnership of three major health systems formed to enhance care in the Rocky Mountain Front Range region.

SCOPE:

BACKGROUND, CONTEXT, INCIDENCE:

Impact of adverse perioperative outcomes: Despite a significant drop in rates of perioperative mortality and morbidity over the last 20 years, these adverse outcomes of surgery remain of great concern to patients, their families, surgical teams, health care payers, and society. For major surgical procedures covered by the American College of Surgeons' National Surgical Quality Improvement Program (ACS NSQIP), one or more perioperative complications occur in 12.6% (287,012/2,275,240) and all cause death in 1.4% (31,568/2,275,240) of patients within 30 days of surgery [Unpublished data from analyses of the ACS NSQIP Participant User File (2005 – 2012)]. Costs of hospitalizations of patients experiencing a perioperative complication are up to five times that of patients without a complication.(1, 2) The occurrence of a perioperative complication is strongly associated with decreased long-term survival beyond 30 days following major surgery.(3) Both perioperative mortality and morbidity are associated with deficits in quality of care assessed by chart review or site visitors blinded to these outcome rates.(4, 5) Thus, these should be amenable to interventions.

Surgical risk: Most surgical procedures carry some risk of adverse outcome(s) ranging from an easily-treated superficial wound infection following a minor skin procedure to death during an aortic aneurysm repair. It is a requirement of ethical care that the patient be informed by the surgical team not only of the risk of the proposed procedure, but also alternative care options and associated risks. The content of the patient counseling of risk of adverse outcomes may vary from: 1) A qualitative statement (e.g., low, medium, high) based on past surgical experience; to 2) Quoting the average risk for the proposed procedure published in the literature; to 3) The integration of the average risk of the procedure with patient-specific risk based on relevant characteristics of that patient using multivariable statistical models. Patient-centered care also requires that the patient's (and often the family's) values and needs be included in the decision to undergo surgery. Finally, with health care costs approaching 20% of gross domestic product, many feel that the costs of the procedure to be borne by the patient and society should be included in the preoperative discussion with the patient.(6)

Despite a general consensus on the above and well-established methods for calculating patient-specific risk, such risk estimates are rarely available preoperatively to any of the stakeholders: the patient, the patient's family, the surgical team, or clinical and hospital leadership. This is partly an information technology problem, as patient-specific risks are currently being calculated <u>postoperatively</u> to risk-adjust adverse outcomes rates as measures of quality of care. Two prominent examples of this are the ACS NSQIP(7-11) and the Veteran Health Administration's Surgical Quality Improvement Program (VASQIP),(12-14) on which the ACS NSQIP was based. Two of the Co-Investigators on this grant (KEH & WGH) played important roles in the development and implementation of these programs beginning in the mid-1980s. These two, widely-respected programs calculate patient-specific risk for several hundred thousand patients undergoing surgery at more than 600 hospitals annually in the U.S. and internationally. However, the required data collection of patient risk factors and outcomes is done postoperatively by manual chart abstraction by highly trained, but costly, reviewers. With the exception of two brief articles in the 1990s,(15, 16) we have found no other reports of sustained programs for data collection and risk calculation to produce <u>preoperative</u>,

quantitative, patient-specific estimates of surgical risk, nor of sharing these risks estimates with the patient, family, and surgical team. There are likely multiple reasons for this, ranging from the burden of data collection to uncertainties about how to best convey this risk information to patients. The VASQIP and ACS NSQIP each collect data on more than 150 pre-, intra-, and postoperative variables. The preoperative variables largely relate to the patient's risk for adverse outcome(s); intraoperative variables include some specifics of the procedure (e.g., duration, anesthetic management and a few adverse outcomes such as intraoperative cardiac arrest); and postoperative variables include morbidity, mortality, and length of stay. The data collection burden for both the VASQIP and ACS NSQIP has mandated representative sampling schemes limiting the number of patients evaluated to about 1,400 patients per nurse reviewer per year, which represents only a minority of surgical patients in most large hospitals. The focus of our study was to enhance preoperative shared decision-making with quantitative estimates of risk available preoperatively to include as many surgical patients as possible. We believe this is feasible through: 1) Limiting the number of preoperative variables to only those required for accurate risk assessment; 2) Automating much of the data collection from the EHR; and 3) Limited data input by the surgical team.

The SURPAS model identifies patients at increased risk of adverse perioperative outcomes and focuses on patient-centered risk communication. This knowledge can also be used by the anesthesiology and surgical teams to facilitate preoperative optimization to decrease postoperative adverse outcomes. We hypothesize that preoperative, quantitative, risk assessment is feasible and deemed useful through a combination of stakeholder engagement, minimization of the data collection burden through the use of parsimonious risk models, and integration with the required preoperative assessment facilitated by the EHR. Full implementation of this model should increase patient knowledge of their surgical risk; and decrease patient decisional anxiety, perioperative adverse events, hospital readmissions, and discretionary surgical procedures.

Parsimonious risk model development: A critical step in achieving buy-in for SURPAS is minimizing additional time and effort needed for use of the SURPAS interface by clinicians and supporting staff. To accomplish this we have completed analyses that: 1) Minimize the number of preoperative risk variables required for accurate prediction of risk of operative mortality and morbidity (i.e. a parsimonious risk model); 2) Minimize the number of risk models by datadriven grouping of perioperative complications; and 3) Incorporate the risk data into a portion of the preoperative note to be completed by surgical team members, including documenting that risks were discussed with the patient. With internal funds provided by the University of Colorado Department of Surgery (DOS) and the Adult and Child Consortium for Health Outcomes Research and Delivery Science (ACCORDS), these tasks have been completed.(17-20) Risk variables available for development of multivariable risk models almost always carry redundant prognostic information when there are more than just a few. A major goal of risk modeling algorithms (e.g., stepwise logistic regression) is to select and rank those variables most predictive of the outcome, while dropping those least predictive. To determine the minimum number of risk variables for accurate prediction of outcomes, we analyzed the ACS NSQIP Participant Use File (PUF) of de-identified data on >2.3 million operations, 2005-2012. Using forward selection stepwise logistic regression, we calculated the cumulative c-index and

the proportion of the maximum c-index (that with all significant (p <0.05) variables in the model) at each step.

We began our work by using the statistical technique of factor analysis to reduce the number of ACS NSQIP postoperative complications from 18 to 6 by grouping similar complications together (infectious, pulmonary, cardiovascular, renal, thromboembolic, and neurologic). (18) We next demonstrated that: 1) Surgical specialty-specific prediction models generally do not improve model discrimination (c-index) or calibration (Hosmer-Lemeshow analyses) compared to generic models constructed using ACS NSQIP data from all surgical specialties combined; (19) and 2) Including preoperative laboratory values provides little improvement in discrimination or calibration at the expense of including more variables with large amounts of missing data. (19) In a final step, we ascertained the most important predictor variables (on the basis of forward stepwise logistic regression) for each of the eight outcome variables (mortality, one or more complications, and the six complication groups). These included American Society of Anesthesiology physical status classification (ASA class), work relative value unit (RVU, a measure of operation complexity), inpatient/outpatient operation, systemic sepsis, primary surgeon specialty, patient functional status prior to surgery, patient age, and emergency operation. These 8 variables accounted for ≥98% of the c-index of the models including all of the 28 non-laboratory preoperative NSQIP variables.(20)

SETTINGS:

This study was performed in the Department of Surgery, University of Colorado School of Medicine, and at the affiliated and co-located University of Colorado Hospital.

PARTICIPANTS:

Stakeholders who participated in focus groups and individual interviews included Department of Surgery and University of Colorado Hospital (UCH) administrative leadership, surgical teams composed of physicians, nurses, physician assistants, and surgical patients. Trial participants were surgeon faculty members in the University of Colorado School of Medicine Department of Surgery, advanced practice providers in the UCH Preprocedure Services and their patients.

METHODS:

Specific Aim 1: Apply a Framework of HIT Adoption to Engage Key Stakeholders: We studied the use and usefulness of SURPAS through the collection and application of qualitative and quantitative data from key stakeholders. We broadly defined these stakeholders as individuals and groups who will impact the outcomes and resource utilization of surgery performed at UCH through the direct use of SURPAS or from information generated through its use: 1) Patients undergoing surgery at UCH; 2) Surgical team members; and 3) DOS and the UCH administration. Surgical team members included those directly delivering care to surgical patients: the responsible surgeon; anesthesiologists and anesthetists; intensivists; surgical trainees; clinic nurse practitioners; other nurses caring for surgical patients; and physician assistants. The DOS and the UCH administration includes: the DOS Chair; Chiefs of surgical divisions reporting to the DOS Chair; the Chair of the DOS NSQIP Steering Committee; the head of the UCH quality improvement team; the Chief Medical Information Officer; and the Co-Chairs of the UCH Information Technology Decision Support Group.

"Town Hall" meeting to present the project and achieve stakeholder buy-in: One "town hall" style meeting was held at the beginning of the study to introduce the project to stakeholders from the DOS and the UCH to achieve collective buy-in, and to define key issues and concerns relevant to project success. The qualitative research team, led by Dr. Lambert-Kerzner, developed a topic guide to accomplish the goals of the meeting and guide discussion. The one hour meeting was recorded and professionally transcribed.(21) A second member of the research team took field notes, enumerated the attendees, and recorded dialogue to supplement digital recordings with non-verbal behavior. This process for record keeping and data integration was maintained throughout subsequent group meetings.

Focus groups/interviews to identify facilitators and barriers to use of SURPAS:
Focus groups: The focus group (FG) is the best method to investigate facilitators and barriers, particularly when the degree of consensus among group members may be low.(22) It is also appropriate for gaining a better understanding of how the target group members think and learn about processes.(23) The qualitative research team, led by Dr. Lambert-Kerzner, developed FG guides designed to elicit the relevant data. At recruitment, the FG facilitator (RAM) discussed the nature of the study and participation with each participant. Prior to starting each FG, a written information sheet was introduced, emphasizing the voluntary nature of participation and the need for confidentiality among FG participants. Each 60 minute FG was guided by a timed agenda outlining major topics of interest and sequence of planned discussion. The facilitator demonstrated a mock-up of the SURPAS user interface to allow for a more informed discussion. FGs met at both the beginning and towards the end of the study period to evaluate SURPAS as it evolved during the course of the project.

Surgical providers: Surgical providers were recruited to participate in one 60 minute focus group at the beginning and one at the completion of the study. This elicited information regarding potential strengths, weaknesses, opportunities, integration into workflow processes, and threats to acceptance and use of SURPAS.

Hospital and clinical administrators: Individual interviews with UCH hospital and clinical administrators were conducted to identify facilitators and barriers to acceptance and use of SURPAS. The goals of these FGs and interviews was similar to that of surgical providers, but focused on the participants' administrative roles. Data were collected allowing the research

team to understand the time, effort, and associated costs of SURPAS from the perspective of these administrators.

Surgical patients: Patients were recruited to participate in 60 minute FGs if they were \geq 18 years of age and underwent an operation in one of the nine specialties accounted for in SURPAS within 365 days of the beginning of the study. Invitation letters were sent to patients and respondents registered for one of two FGs of approximately 10 surgical patients each. Participants were paid \$75/FG. These FGs sought to determine patients' interest in receiving quantitative personalized risk information preoperatively and their preferred presentation format for risk information. A FG of the initial patient participants was performed towards the completion of the study to demonstrate the revised SURPAS tool and obtain additional feedback.

Use of this framework to define, synthesize, and revise SURPAS: The goal of the qualitative analysis was to identify the stakeholders' perceived facilitators of and barriers to acceptance and use of SURPAS. The perceived impact, uptake, feasibility, acceptability, and sustainability of the tool were analyzed. The words participants used, their beliefs and needs, and desired strategies for intervention were described. Consistent with qualitative methodology, analysis was planned as a continuous process beginning with initial data collection and continuing throughout and beyond the data generation period.(24) Data were coded following a process of initial review, with labeling of data by content, process, or impressions of the person coding. Dr. Lambert-Kerzner and a research assistant (KLF) independently coded 10% of the data, discussed codes, established inter-coder reliability, and created an initial master code list. The research assistant coded the remaining data using this code list. Following initial coding, transcriptions of FG data were analyzed for themes, patterns and the degree of consensus about particular topics discussed in FGs to develop a matrix analysis.(25)

Data synthesis and trustworthiness: The synthesis stage of data analysis involved triangulating the findings from FGs and interviews, making refinements in the explanatory models and themes, and reviewing the literature for findings from similar investigations. Triangulation is "the most effective way to ensure reliability and validity" of qualitative data by obtaining "comparable, confirmatory data from multiple sources," (26) and enhanced the trustworthiness of the data. (27) The trustworthiness of study findings was heightened through attention to the credibility, transferability, dependability, and reproducibility. (28) Triangulation involved meetings of the research team to engage in reflexive analysis, including reviewing together the range of data, examining contradictory data, and considering the possibility of symbolic meaning or social desirability underlying apparent discrepancies.

Specific Aim 2: A multi-methods approach to develop, implement, and refine SURPAS

Identify and map variables known to predict operative risk available in the UCH Epic

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EHR: The UCH Epic staff determined for us that our eight SURPAS predictor variables could technically be mapped to discrete elements in the UCH Epic EHR. However, data quality and timeliness in relation to the patient's preoperative visit needed to be evaluated as part of the current proposal. The validity of the mapping process was assessed by comparing automatically extracted data to those abstracted by our NSQIP reviewers for the UCH patients entered into the ACS NSQIP. During SURPAS development and validation, UCH patient data were abstracted from the Epic Clarity reporting system, our institutional patient data warehouse used for

reporting. During clinical evaluation, data were abstracted from real-time Epic Cache/Chronicles EHR.

Software tools for data extraction, data input, and operative risk communication: The SURPAS tool was developed and installed into the UCH Epic EHR by AgileMD (San Francisco, CA), a health information technology company under contract with UCHealth. In SURPAS, a custom preoperative data form appears to the provider at the beginning of a pre-operative visit. This form is pre-populated with values for the SURPAS data elements from the Epic EHR found to be of sufficiently high data quality and completeness at the patient's preoperative visit. The provider only needs to fill in missing values for the key data elements. The SURPAS risk estimates are calculated and displayed in Epic for the provider. The patient's individual risk estimates are compared to ACS NSQIP national averages for the average patient undergoing the same operation. A preoperative note is also automatically written into the patient's EHR. A printout of the patient's risks compared to national averages in the form of pictographs can also be made and printed for the patients to keep. Input and output data from the patient encounter are also stored for future analysis of the dissemination and use of SURPAS.

Implement initial delivery methods to providers and patients at the point-of-care: We limited the trial implementation to 6-12 volunteer surgeons. For each surgical specialty clinic in which SURPAS was to be trialed, ALK visited the clinic manager to assess the readiness of the clinical environment. Clinical administrators were shown the SURPAS tool and asked their opinions about the tool and how they believe it would affect the workflow of the clinic and or the behaviors of the clinical staff, including surgeons.

For the trial implementation process, we aimed for enrollment of 200 surgical patients to provide us with the feedback about their experience of having the SURPAS tool as part of their pre-surgical clinic encounter to guide revisions to the decision aid tool. We asked patients and providers to complete a survey about their experience after the encounter.

The initial trial implementation of SURPAS involved surgeons and their adult (≥18 years old) patients who were undergoing a surgical procedure and seen as an outpatient in preoperative consultation through one of the surgical clinics by one of the surgeons who volunteered to participate. Exclusion criteria were patients <18 years of age, patients undergoing emergency procedures, pregnant women or fetuses, prisoners or those on probation or alternative sentencing and decisionally challenged patients.

We observed a subset of the clinical interactions between the patient and the surgeons using SURPAS and interviewed both about their opinions of the SURPAS tool, their experience using the SURPAS tool, and any suggestions to improve the tool and the implementation process. Individual semi-structured interviews were performed with surgical providers and patients after their clinic visit using an interview guide.

Iterative feedback on SURPAS CDS application: We reconvened our focus group of surgical providers and patients near the completion of the trial implementation of SURPAS to give us input on the ease of use, utility, value and content of this software module.

Dissemination and Implementation Planning: During SURPAS development, we presented progress reports at monthly DOS Surgical Outcomes and Applied Research (SOAR) program meetings and annually at DOS Grand Rounds presentations. Further local dissemination across the University of Colorado School of Medicine was planned via institutional research symposia. Regional and national dissemination was planned. Additional synthesis of a D&I plan was achieved during the above tasks. This study protocol was approved by the Colorado Multiple Institution Review Board.

RESULTS:

Principal Findings:

We were successfully able to develop a user-friendly SURPAS interface in the local EHR. The stakeholder focus groups and interviews informed us throughout this development, optimizing both the provider's interface and the patient-centric risk prediction output. Two of seven independent variables could be automatically entered into SURPAS from the EHR. Patients and physicians found SURPAS to be useful for preoperative risk assessment. Patients reflected that this improved their understanding and comfort with the planned operation. Patients had no preconceived idea of surgical risk. Surgeons were unable to reliably predict risk when a patient was at a greater than minimal risk. The findings from the local limited implementation of SURPAS are guiding our scaling up of SURPAS for D&I in our broader health system.

Outcomes:

We present the results and discussion of our grant along the lines of the resulting and ongoing publication preparations. These are as follows:

Challenges with Integration of a Surgical Risk Preoperative Assessment System into the Local Electronic Health Record: In order to determine the preoperative utility of data in the EHR required to predict the risk of common postoperative adverse outcomes using the SURPAS clinical decision support tool, we determined the accuracy and availability of the eight required predictor variables within our institution's EHR at the time of the patient's surgical preoperative encounter. Variables required for SURPAS were age, American Society of Anesthesiology physical status classification, systemic sepsis, work Relative Value Unit, in-/outpatient operation, surgeon specialty, emergency status, and functional health status. We compared the EHR values to the values ascertained by nurses through medical chart review for 5,205 patients entered into the database of the ACS NSQIP from July, 2013, to January, 2016. Acceptable accuracy was considered a Kappa statistic or Pearson correlation coefficient >0.8 for the comparison of variables between the local EHR and NSQIP data. Availability of variables at the preoperative visit ≥95% of the time was defined as acceptable for use in SURPAS. Six SURPAS predictor variables had Kappa statistics or Pearson correlation coefficients ≥0.80; preoperative sepsis and functional health status did not. Only age and primary surgeon specialty were ≥95% available at the time of the preoperative visit, resulting in only two of eight predictor variables being accurate and available within the EHR at the preoperative encounter

for reliable use in the SURPAS tool. The other six variables need to be entered by care providers. This is currently in submission for peer-reviewed publication.

Assessment of Attitudes towards Future Implementation of the Surgical Risk Preoperative Assessment System (SURPAS) Tool: A Qualitative Study: Four focus groups with 24 patients, three focus groups with 29 surgical providers and clinic administrators, and five individual interviews with administrative officials were conducted to elicit their perspectives about the development and implementation of SURPAS. Qualitative data collection and analyses, utilizing a matrix analysis approach were used to explore insights regarding SURPAS. All types of participants were positive about SURPAS and provided suggestions to improve and address concerns regarding it. For healthcare personnel, three major themes emerged: 1) The SURPAS tool - Important work especially helpful for high risk patients, yet not a substitute for clinical judgment; 2) Benefits of SURPAS to the risk assessment process - Improves the risk assessment processes, enhances patients' participation in shared decision-making process, and creates a permanent record; and 3) Facilitators and barriers of implementation of SURPAS -Easy to incorporate into clinical practice despite of surgical providers' resistance to adoption of new technology. For patients, three major themes emerged: 1) Past experience of preoperative risk assessment discussions – Patients frequently were not made aware of possible complications that occurred; 2) The SURPAS tool – All patients liked SURPAS and believed having printed material would be useful to guide discussions and facilitate remembering conversations with the providers; and 3) Potential concerns with having risk assessment information – Patients were mixed in deciding to have an operation with high risks. Systematically capturing data from the beginning of the implementation process from key stakeholders (patients, surgical providers, clinical staff, and administrators) that includes adaptations to the tool and implementation process will help to inform pragmatic approaches for implementing the SURPAS tool in various settings, scaling-up, and sustaining it. This has been published in a peer-reviewed journal. (29)

Refinements of SURPAS for Implementation Based Upon Focus Groups of Patients, Surgeons, and Administrators: The focus groups of patients, surgeons, and administrators expressed a number of concerns and/or recommendations for refinements to the prototype SURPAS tool:

- 1. Although a factor analysis of the postoperative complications suggested six clusters of complications, some of the complications that were clustered together are likely addressed by different processes of care; therefore, some should be made distinct postoperative adverse outcomes (e.g., cardiac complications and bleeding were separated; surgical site infections and urinary tract infections were separated, etc.);
- 2. Hospitalizations causing the patient to spend time away from home and family were identified as important patient concerns; therefore, the risk of unplanned re-hospitalization following surgery should be included as an adverse postoperative outcome;
- 3. Related to the eight preoperative predictor variables, there was concern about the adequacy of the wRVU of the primary operation accounting for the complexity of the operation, particularly in operations involving multiple CPT codes;
- 4. Also related to the preoperative variables, preliminary work in integrating SURPAS into the local EHR suggested that systemic sepsis within 48 hours of surgery would be a difficult variable to assess at the preoperative encounter;

- 5. The SURPAS tool should provide documentation of the risk information and discussion with the patient and family in the patient's medical record;
- 6. The SURPAS tool should provide risk information to the patients and their families in a printed and easily understood format to help them understand and remember details of the informed consent process;
- 7. The SURPAS tool should provide answers to "frequently asked questions" (FAQs) to facilitate the implementation of the tool and to foster collaborative discussions with patients; and
- 8. One patient who experienced debilitating depression after his operation suggested incorporating a risk for adverse psychological or cognitive effects postoperatively. Some of these concerns/recommendations needed to be addressed through further analysis of the ACS NSQIP database (Items #1, 2, 3, 4); some could be addressed by adding features to the SURPAS tool (Items #5, 6, 7); and another required the collection of an additional outcome (Item #8). Therefore, we performed the above analyses and revisions to the SURPAS tool in response to these concerns and recommendations.

We found that elimination of the preoperative sepsis predictor variable had very little effect on the c-indexes and Brier scores for predicting the eleven outcome variables. C-indexes were decreased by 0.001 to 0.013 units, or percent decreases of 0.1% to 1.7%, while Brier scores were increased by 0.0000 to 0.0018 units, or percent increases of 0.0% to 3.9%.

When CPT event rate was substituted for preoperative sepsis in a new eight-variable model, c-indexes were increased by 0.002 to 0.031 units, or percent increases of 0.2% to 4.0%. Brier scores did not change for five of the 11 adverse postoperative outcomes, were reduced for four additional outcomes by 0.0001 to 0.0024 units (percent reductions of -0.2% to -2.8%), and were increased for only two outcomes by 0.0001 units (percent increase of 1.0%) and 0.0005 units (percent increase of 2.2%). The c-index is above 0.90 for one outcome (mortality, 0.928), between 0.80 and 0.89 for seven outcomes (0.893 for pulmonary, 0.875 for bleeding/transfusion, 0.871 for cardiac, 0.863 for renal, 0.840 for stroke, 0.823 for overall morbidity, and 0.805 for infection), and between 0.70 and 0.79 for three outcomes (0.788 for VTE, 0.776 for UTI, and 0.723 for unplanned readmission).

To examine whether adding an indicator variable for multiple CPT codes would improve the SURPAS prediction models, we compared nine-variable models (with the addition of an indicator variable for multiple CPT codes) to our eight-variable models. The addition of the indicator variable minimally increased the c-indexes by 0.000 to 0.002 units (0.0% to 0.2%), and minimally decreased the Brier scores by 0.0000 to 0.0004 units (decreases of 0.0% to 0.5%). The greatest effect was on the bleeding/transfusion postoperative adverse outcome, but the increase in c-index was only 0.2% and the decrease in Brier score was only 0.5%.

CPT specific event rate was the first variable to enter the models for nine of the 11 adverse postoperative outcomes (all but the models for 30-day mortality and cardiac complications in which ASA class was the first variable to enter). Comparing the c-indexes and Brier scores of the prediction models in the developmental and test datasets, only one of the 11 c-indexes (for UTI) showed the expected decline going from the developmental to the test dataset and that decline was only 0.001 unit, and all changes in Brier scores from the development to the test dataset were within 0.002 units, indicating excellent internal validation.

We revised the SURPAS EHR interface tool based on suggestions by focus group participants. The tool was developed to include documentation of the risk assessment within the EHR. A

visual display was developed comparing the predicted patient risk to the national average for patients who have undergone the same procedure. This was made in the format almost unanimously requested by patients, and developed into a PDF which can be printed and handed out to the patient during the preoperative encounter. A user guide with FAQs was developed and added to SURPAS to facilitate the implementation of the tool. The SURPAS computer program was developed by AgileMD (San Francisco, CA), a health IT company contracted by UCHealth for all extra-EHR computer development. Manuscript in preparation.

Accurate Preoperative Prediction of Unplanned 30-day Postoperative Readmission Using Eight Predictor Variables: Patient participants of the focus groups wanted to receive prediction of unplanned postoperative readmissions. Therefore, a new algorithm for unplanned readmission was developed in the same manner that the SURPAS risk algorithms were. Data from the ACS NSQIP dataset were used to compare two risk prediction models. The first model included all available preoperative variables and was compared to the original eight variable SURPAS model. C-indexes, Hosmer-Lemeshow analyses, and Brier scores were compared to determine model accuracy.

5.3% of patients experienced an unplanned readmission. The SURPAS model's c-index, 0.725, was 98.4% of that of the full model, 0.733. Hosmer-Lemeshow analyses indicated similar calibration between the two models.

The eight predictor variables identified in SURPAS detect patients at risk for unplanned readmission as accurately as the full model developed from all available preoperative variables in the ACS NSQIP dataset. The unplanned readmission model has been integrated into the SURPAS tool. The manuscript describing this is in preparation for peer-reviewed publication. Limited Clinical Implementation of SURPAS Tool via the Local EHR: The limited clinical implementation of SURPAS was performed in 177 patients in the clinics of 7 surgeons of a broad array of specialties, and in 20 patients in the Preprocedure Services (PPS) Clinic. Each surgeon was administered a survey after every use of SURPAS. Each patient was surveyed after surgical consent was obtained. All of the surgeons and 30 of the patients were interviewed. The majority of patients reported having a discussion about their surgical risk (85.3% [168/197]) with their surgeon (98.8% [166/168]) vs other provider team members; received the SURPAS tool (98.2% [165/168]); and had it explained to them by their surgeon (92.7% [153/165]). After receiving and discussing their risk estimates, the majority of the patients stated that they understood their risk of surgery 'very well' (88.1% [148/168]) or 'quite well' (10.7% [18/168]) and most patients found the SURPAS tool to be 'very helpful' (60.0% [99/165]) or 'helpful' (32.7% [54/165]) with only a few finding it 'somewhat helpful' (4.9% [8/165]).

"I liked it. It was pretty informative. It made me more comfortable with the idea of the operation, knowing what my chances were. Usually you're told all of the things that could happen to you. The last one they tell you is, of course, death. That's the only thing that you remember is the death. Yes. This clarified a lot of things." (Patient #T44/171)
In a few cases, the patients reported that their risk estimates affected the decision to have or not to have the operation (15.8% [26/165]) or prompted deeper discussions with the provider (15.8% [26/165]). This suggests that the SURPAS tool can aid patient decision making during the preoperative encounter.

"It makes you think about how risky it (surgery) might be or how—just kind of puts you into the frame of mind of understanding all the risks involved—all the complications that might arise from it." (Patient #T1/1)

Patients who had higher risk scores for 30-day morbidity (4.5% vs 2.8%: p=0.04) and unplanned readmission (4.9% vs 2.6%: p=0.03) were more likely to desire to have a deeper discussion with their provider, further supporting that the SURPAS tool can aid decision making. However, there was no other association with patient risk estimates and how they responded to the other questions about the SURPAS tool. This might suggest that patients do not necessarily have a preconceived estimate of their risk of adverse postoperative outcomes.

"The other thing I would say, the other number that struck me was the risk of rehospitalization after discharge. I think that came out to 25 percent. I think that surprised me. I thought that was high. However, that hasn't been the case for me. That was a surprise and made me realize that it seems like the most risk is actually after the surgery." (Patient #V18/162)

Surgeons responded that they discussed the patient's risk with them the majority of the time (83.8% [165/197]) and that they provided the SURPAS handout to the patient (83.3% [164/197]) and explained the document to them (99.4% [163/164]). Most of the surgeons reported that the risk document given to the patients was 'very helpful' (10.7% [21/197]) or 'helpful' (48.7% [96/197]) but there were a few that found the risk document to be 'somewhat helpful' (23.4% [46/197]) or 'not helpful' (9.6% [19/197]).

"I think that's very beneficial, because it engages the patient, it empowers them with additional health literacy, it informs them, and ideally relates to them that they are not only a consumer of healthcare, but they have power to change their own outcomes based on their own behavior and their own health." (Surgeon #2)

Surgeons stated that the SURPAS tool changed the interaction with the patients about half of the time (44.7% 88/197]) with almost all changed beneficially (94.3% [83/88]). Rarely did surgeons report that the SURPAS tool affected the decision to do or not do the operation (1.5% 3/197]), changed any aspect of the preoperative work up (4.6% [9/197]), postoperative care (2.0% [4/197]), or patient management (1.5% 3/197]).

"We'll see patients in clinic who are nursing home residents who, let's say, I would feel that if I did an operation, that would have too much of a risk for surgery, so we don't wanna do it. The patient comes to see a surgeon, expects an operation, so I think it would improve the patient's care if I could show them the true risks of the operation. If their risk of dying from surgery is 30 percent, then they probably wouldn't go with it, so it probably will help them out... Then, if we can figure out interventions that would decrease those risks, I think that would be helpful, as well. We have some things that are known, like for wound infection, giving antibiotics, preoperatively prepping correctly, normothermia, which we are supposed to do anyways, no matter what SURPAS shows, but maybe there are some specific risks of an operation. Let's say if I have—if I need to revascularize someone's lower extremity, and I can do it open versus endovascular, and if it shows that the open surgery has way too much risk associated with it, I may go with the endovascular operation." (Provider #10)

Finally, there were significant associations between patient risk estimates and surgeon's attitudes about the SURPAS tool: 1) The surgeons thought the SURPAS tool was more helpful when the patient's risk was high, but not as helpful when the patient's risk was low; 2) The

surgeons thought that the SURPAS tool prompted more dialog with the patient when the patient's risk was high; and 3) The surgeon's estimate of risk was closer to the SURPAS estimates when the patient risk was low compared to when the patient risk was high.

"I have used it before when I was on call for trauma... I used it for a patient that was sicker and needed a colon operation. That, I did find to be – he was too sick to actually go through it with him and I wasn't sitting in front of my computer when I talked to the family, but I used it to more accurately represent to his family what the risks were and I found that helpful, for sure." (Provider # 3)

The manuscript describing this is in preparation for peer-reviewed publication.

Use of the Consolidated Framework for Implementation Research (CFIR) to Guide the Translational Process from Design to Broad Utilization of the Surgical Risk Preoperative Assessment System: A Formative Evaluation: This two-phased formative evaluation included a contextual baseline assessment utilizing focus groups of providers and patients and individual interviews of administrators, and a trial implementation to pilot the SURPAS tool including individual interviews with clinic administrators, surgical care providers, and patients. A qualitative matrix analysis approach, supported by coding data to the CFIR constructs, identified elements influencing the D&I of SURPAS, with adaptations for the process and tool. The contextual baseline assessment and the trial implementation identified three CFIR domains, with specific constructs, that participants believed would strongly influence the effectiveness of the implementation of SURPAS: The importance of patients' perspectives (Outer Setting); The quality of SURPAS (Intervention Characteristic); and Integration of SURPAS in the EHR (Inner Setting). The trial implementation also recognized: Providers support of SURPAS (Characteristics of Individuals); and the ease of integration of SURPAS into the workflow (Process) as profound components. Tension emerged between patients' preference for the provision of risk information and providers' concern about additional clinic time required for formal risk discussion with low-risk patients. The domains and constructs identified in the contextual baseline assessment helped inform the trial implementation. Confirmatory and additional findings from the trial implementation further shaped the multi-component strategy for future scale-up.

Systematically capturing constructs from the beginning of the design through the implementation process can guide the multi-component strategy for future scale-up and assign relative importance to various themed constructs within the CFIR framework. This allows key stakeholders to empower the D&I of SURPAS at multiple levels and times, continuously optimizing the process. The manuscript describing this is in preparation for peer-reviewed publication.

Additional D&I of SURPAS:

We have engaged in the following local and national presentations of SURPAS:

- 1. Meguid, R.A.: "Surgical Risk Preoperative Assessment System Development of a Novel Risk Assessment System." Oral presentation at the Surgical Outcomes Club, Monthly Work In Progress Seminar, national webinar, April 21, 2016.
- 2. Meguid, R.A.: "Surgical Risk Preoperative Assessment System Development of a Novel Risk Assessment System." Oral presentation at Grand Rounds, Division of Urology, Department of Surgery, University of Colorado School of Medicine, Aurora, CO, June 6, 2016.

- 3. Meguid, R.A.: Surgical Risk Preoperative Assessment System Development of a Novel Risk Assessment System. Oral presentation at Grand Rounds, Department of Surgery, University of Colorado School of Medicine, Aurora, CO, September 19, 2016.
- 4. Meguid, R.A.: Surgical Risk Preoperative Assessment System Development of a Novel Risk Assessment System. Oral presentation at Grand Rounds, Department of Anesthesiology and Critical Care, University of Colorado School of Medicine, Aurora, CO, December 5, 2016.
- 5. Lambert-Kerzner, A., Lynett, K., Hammermeister, K.E., Henderson, W.G., Meguid, R.A.: Formative Evaluation of the Surgical Risk Preoperative Assessment System (SURPAS): Use of Consolidated Framework for Implementation Research (CFIR) to guide the Implementation Process. Poster presentation at the 9th Annual Conference on the Science of Dissemination and Implementation, the National Institutes of Health & AcademyHealth, Washington, DC, December 15, 2016.
- 6. Meguid, R.A.: Surgical Risk Preoperative Assessment System Development of a Novel Risk Assessment System. Oral presentation at the American College of Surgeons National Surgical Quality Improvement Program, Monthly Seminar, national webinar, April 27, 2017.
- 7. Meguid, R.A., Bronsert, M.R., Juarez-Colunga, E., Hammermeister, K.E., and Henderson, W.G.: Development of the Parsimonious Surgical Risk Preoperative Assessment System for Accurate Preoperative Prediction of Common Adverse Outcomes. Oral and poster presentation at the ACS Quality and Safety Conference 2017 annual meeting, New York City, NY, July 22-25, 2017.
- 8. Lambert-Kerzner, A., Overbey, D., Aasen, D., Damschroder, L., Henderson, W.G., Hammermeister, K.E., Bronsert, M.R., Meguid, R.A.: Using the Consolidated Framework for Implementation Research (CFIR) to guide the Translational Process of the Surgical Risk Preoperative Assessment System (SURPAS). Poster presentation at the 10th Annual Conference on the Science of Dissemination and Implementation, the National Institutes of Health & AcademyHealth, Washington, DC, December 15, 2017.

This resulted in the successful awarding of an intramural grant entitled "Scaling of SURPAS for Dissemination & Implementation," which is underway.

CONCLUSIONS:

Based on the input of patients, surgical providers and administrators, we developed an EHR-based interface for SURPAS. We made iterative changes to SURPAS after an approximately 200 patient trial, with interviews of surgeons using SURPAS and patients viewing the output of SURPAS. Post-development focus groups of surgical providers and patients yielded positive feedback. We have developed a strategy for D&I of SURPAS at UCH and UCHealth, and have been awarded an intramural grant to begin D&I at UCH.

We view the development, implementation, and dissemination of the SURPAS tool at UCHealth as a long-term project. In addition to exploring patient reported outcomes, future research involving SURPAS will need to address issues such as how to define patients at "high risk" for adverse outcomes, and identifying and testing processes of care that may mitigate the risk in these "high risk" patients and consequently prevent postoperative complications in these patients.

SIGNIFICANCE:

The successful development of a user-friendly SURPAS interface in the local electronic health record is a significant step towards routine, standardized preoperative risk assessment. The development of the SURPAS tool has been informed through stakeholder engagement. To the best of the authors' awareness this is novel among surgical risk assessment tools in use. Unlike surgical risk assessment tools in use, SURPAS has been studied and found to be useful and usable by the patients and providers.

IMPLICATIONS:

Subsequent D&I of SURPAS will facilitate routine, standardized preoperative risk assessment. This may improve patient and family engagement during decision making. Awareness of specific postoperative risks may facilitate preoperative optimization of patients to decrease postoperative complications. Ultimately, based on our limited implementation, widespread use of SURPAS is likely to improve patient and provider awareness of perioperative risks, and satisfaction with the shared decision making process.

LIST OF PUBLICATIONS AND PRODUCTS:

- 1. Lambert-Kerzner, A., Ford, K.L., Hammermeister, K.E., Henderson, W.G., Bronsert, M.R., Meguid, R.A.: Assessment of Attitudes towards Future Implementation of the Surgical Risk Preoperative Assessment System (SURPAS) Tool: A Qualitative Study. *Patient Safety in Surgery* on April 29, 2018. In Press. PSIS-D-18-00015
- 2. Surgical Risk Preoperative Assessment System (SURPAS) Clinical Decision Support tool https://agile.md/iug06pno
- 3. Meguid, R.A.: "Surgical Risk Preoperative Assessment System Development of a Novel Risk Assessment System." Oral presentation at the Surgical Outcomes Club, Monthly Work In Progress Seminar, national webinar, April 21, 2016.
- 4. Meguid, R.A.: "Surgical Risk Preoperative Assessment System Development of a Novel Risk Assessment System." Oral presentation at Grand Rounds, Division of Urology, Department of Surgery, University of Colorado School of Medicine, Aurora, CO, June 6, 2016.
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